510(k) SUMMARY

A. Submitter Information:

OCT 11 2002

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-1787 Fax
Contact:	Florence A. Caikoski
Date Prepared:	June 25, 2002

B. Trade Name:	Medcomp Pediatric Ash Split Cath™ XL
Common Name:	Hemodialysis Catheter, Implanted
Classification:	78 MSD
C.F.R. Section:	876.5540

C. Predicate Device:	K013162 Medcomp Ash Split Cath™ W/Strain Relief K984022 Arrow Pediatric Two-Lumen Hemodialysis Catheter

D. Device Description:

The Medcomp Pediatric Ash Split Cath™ XL is a 10F polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, tapered at the distal tip, with six side holes. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement. A polyurethane sleeve is positioned between the hub to cuff location.

The lumens are connected to the extensions via a soft pliable hub with suture wing. Red and blue luer connectors and clamps identify the arterial and venous extensions. The clamps incorporate I.D. Rings which indicate priming volume and site care information.

E. Intended Use:

The Medcomp Pediatric Ash Split Cath™ XL is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in pediatric, adolescent, and adult patients as determined by the prescribing physician. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian and femoral vein.

F. Comparison to Predicate Device:

The proposed device is a product line extension to the Medcomp legally marketed device, and is identical in design and materials.

The modifications include:

- Pediatric population indication for use
- Change from 14F to 10F outer diameter
- 18cm length
- Femoral insertion site

G. Performance Data:

In-vitro performance data for the proposed device including tensile strength, joint strength, leakage, recirculation, flow performance, and mechanical hemolysis demonstrates this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ms. Florence Caikoski
Regulatory Affairs Associate
MedComp®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K020936
Trade/Device Name: 10F x 18cm Pediatric Ash Split-Cath™ XL, Model ASPC18P-XL, and 10F x 24cm Pediatric Ash Split-Cath™ XL, Model ASPC24P-XL
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: July 15, 2002
Received: July 16, 2002

Dear Ms. Caikowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

David A. Clayman

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020936

INDICATIONS FOR USE

510(k) Number: K020936

Device Name: Medcomp Pediatric Ash Split Cath™ XL

Indications for use:

The Medcomp Pediatric Ash Split Cath™ XL is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in pediatric, adolescent, and adult patients as determined by the prescribing physician. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian and femoral vein.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Jayman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020936